

WHAT IS CLAIMED IS:

1. A process for making homogeneous, thermoreversible gel films comprising the steps of:

(i) heating, hydrating, mixing, solubilizing, and, optionally, de-aerating a film forming composition in an apparatus providing sufficient shear, temperature and residence time to form a homogeneous molten composition, wherein said temperature is at or above the solubilizing temperature of said composition;

(ii) feeding said molten composition into at least one of a mixer, pump or devolatilizer; and

(iii) cooling said homogeneous molten composition at or below its gelling temperature to form said gel films.

2. The process of claim 1, wherein said film forming composition comprises at least one hydrocolloid film former and optionally a plasticizer, bulking agent, pH control agent and second film former.

3. The process of claim 1, wherein said apparatus is a Ross mixer, Stephan processor, extruder, jet cooker or fluid mixing apparatus.

4. The process of claim 1, wherein said molten composition is at least 50% solids.

5. The process of claim 1, wherein said molten composition is at least 60% solids.

6. The process of claim 1, wherein said molten composition is at least 70% solids.
7. The process of claim 1, wherein said molten composition is at least 80% solids.
8. The process of claim 1, wherein said molten composition is at least 90% solids.
9. The process of claim 1, wherein said gel film has a break force of at least 1,000 grams.
10. The process of claim, 1 wherein said gel film has a break force strength of at least 2,500 grams.
11. The process of claim 1, wherein said gel film has a break force strength of at least 4,000 grams.
12. The process of claim 1, wherein said gel film has a break force strength of at least 5,000 grams.
13. The process of claim 1, wherein said gel film has a break force strength of at least 6,000 grams.

14. The process in any of claims 1-13, wherein said molten composition is fed into at least one of a pump, mixer or devolatilizer.

15. The process of claim 2, wherein said hydrocolloid is at least one member selected from the group consisting of a carrageenan, alginate, glucomannan or galactomannan, said plasticizer is at least one member selected from the group consisting of glycerin, sorbitol, maltitol, lactitol, and polyalkylene glycols; said second film former is at least one member selected from the group consisting of a starch, starch derivative, starch hydrozylate, cellulose gum, hydrocolloid, an alkylcellulose ether and a modified alkyl cellulose ether; and said bulking agent is at least one member selected from the group consisting of microcrystalline cellulose, microcrystalline starch, starch, starch derivatives, inulin, and starch hydrozylates.

16. The process of claim 15, wherein said carrageenan is at least one member selected from the group consisting of iota carrageenan, kappa carrageenan and kappa-2 carrageenan; said alginate is propylene glycol alginate, said glucomannan is konjac and said galactomannan is guar gum.

17. The process of claim 1, wherein said solubilizing temperature is greater than the boiling point of the homogeneous molten composition at atmospheric pressure and said heating, hydrating, mixing and solubilizing is conducted above atmospheric pressure.

18. The process in any of claims 1 to 17, wherein said devolatilization is conducted in an extruder.

19. The process in any of claims 1 to 17, wherein said molten composition is fed directly into said mixer, deaerated, depressurized and pumped prior to cooling to or below the molten composition's gelling temperature.

20. A homogeneous, thermoreversible, high solids, low moisture film made from the process in any of claims 1-19.

21. A process for making soft capsules comprising the steps of:

(i) heating, hydrating, mixing, solubilizing and, optionally, de-aerating a high solids, low moisture film forming composition in an apparatus providing sufficient shear, temperature and residence time to form a homogeneous molten composition, wherein said temperature is at or above the solubilizing temperature of said composition;

(ii) feeding said molten composition into at least one of a mixer, pump or devolatilizer;

(iii) cooling said molten composition to or below the gelling temperature of the molten composition to form a homogeneous, thermoreversible gel film; and

(iii) making soft capsules from said gel film.

22. The process of claim 21, wherein said film forming composition comprises at least one hydrocolloid and optionally a plasticizer, bulking agent, a pH control agent and second film former.

23. The process of claim 21, wherein said apparatus is a Ross mixer, extruder, Stephan processor, jet cooker or fluid mixing apparatus.

24. The process of claim 21, wherein said molten composition is at least 50% solids.

25. The process of claim 21, wherein said molten composition is at least 60% solids.

26. The process of claim 21, wherein said molten composition is at least 70% solids.

27. The process of claim 21, wherein said molten composition is at least 80% solids.

28. The process of claim 21, wherein said molten composition is at least 90% solids.

29. The process of claim 21, wherein said gel film has a break force of at least 1,000 grams.

30. The process of claim 21, wherein said gel film has a break force strength of at least 2,500 grams.

31. The process of claim 21, wherein said gel film has a break force strength of at least 4,000 grams.

32. The process of claim 21, wherein said gel film has a break force strength of at least 5,000 grams.

33. The process of claim 21, wherein said gel film has a break force strength of at least 6,000 grams.

34. The process in any one of claims 21-33, wherein said molten composition is fed into an extruder having at least one of a pump, mixer and devolatilizer.

35. The process of claim 22, wherein said hydrocolloid is at least one member selected from the group consisting of a carrageenan, alginate, glucomannan or galactomannan, said plasticizer is at least one member selected from the group consisting of glycerin, sorbitol, maltitol, lactitol, and polyalkylene glycols; said second film former is at least one member selected from the group consisting of a starch, starch derivative, starch hydrozylate, cellulose gum, kappa carrageenan; iota carrageenan, kappa-2 carrageenan, alginates, propylene glycol alginate, polymannan gums, pullulan, dextran, gellan, pectin, an alkylcellulose ether and a modified alkyl cellulose ether; and said bulking agent is at least one member selected from the group consisting of microcrystalline cellulose, microcrystalline starch, starch, starch derivatives, inulin, and starch hydrozylates.

36. The process of claim 35, wherein said carrageenan is at least one member selected from the group consisting of iota carrageenan, kappa carrageenan and kappa-2 carrageenan; said alginate is propylene glycol alginate, said glucomannan is konjac and said galactomannan is guar gum.

37. The process of claim 21, wherein said solubilizing temperature is greater than the boiling point of the homogeneous molten composition at atmospheric pressure and said heating, hydrating, mixing and solubilizing is conducted above atmospheric pressure.

38. The process in any one of claims 21 to 37, wherein said devolatilization is conducted in an extruder.

39. The process in any one of claims 21 to 37, wherein said molten composition is fed directly into said mixer, deaerated, depressurized and pumped prior to cooling to or below the molten composition's gelling temperature.

40. Soft capsules made by the process in any one of claims 21 to 39.

41. A process for making a solid dosage form comprising a fill material encapsulated by a homogeneous, thermoreversible gel film comprising the steps of:

(i) preparing the homogeneous, thermoreversible gel film in accordance with the process in any one of claims 1-19; and

- (ii) encapsulating said fill material in said gel film.

42. The process of claim 41, wherein said fill material is a powder, tablet, caplet, microcapsule or capsule.

43. The solid form of claim 41, wherein said solid form is a hard capsule.

44. A process for preparing a homogeneous gel film delivery system comprising an active substance and a homogeneous, thermoreversible gel film, comprising the steps of:

- (i) preparing the molten composition in any one of claims 1-19; and
- (ii) adding an effective amount of an active substance prior to or after formation of the molten composition: and
- (iii) cooling said molten composition containing said active substance at or below its gelling temperature to form said gel films containing said active substance.

45. The process of claim 44, wherein said active substance is at least one of an oral care agent, a breath freshening agent, a pharmaceutical agent, a nutraceutical agent, a salivary stimulant agent, a vitamin, a mineral, a coloring agent, a sweetener, a flavorant, a fragrance, a food.

46. A delivery system made by the process of claim 44.

47. A process for making homogeneous, thermoreversible gel films comprising the steps of:

(i) heating, hydrating, mixing, solubilizing, and, optionally, deaerating a film forming composition in an apparatus providing sufficient shear, temperature and residence time to form a homogeneous molten composition, wherein said temperature is at or above the solubilizing temperature of said composition; and

(ii) cooling said homogeneous molten composition at or below its gelling temperature to form said gel films.

48. The process of claim 47, wherein said apparatus is a Ross mixer.

49. A process for making soft capsules comprising the steps of:

(i) heating, hydrating, mixing, solubilizing and, optionally, deaerating a high solids, low moisture film forming composition in an apparatus providing sufficient shear, temperature and residence time to form a homogeneous molten composition, wherein said temperature is at or above the solubilizing temperature of said composition;

(ii) cooling said molten composition to or below the gelling temperature of the molten composition to form a homogeneous, thermoreversible gel film; and

(iii) making soft capsules from said gel film.

50. The process of claim 49, wherein said apparatus is a Ross mixer.